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EXAMINER	
HAND, MELANIE JO	

ART UNIT	PAPER NUMBER
3761	

NOTIFICATION DATE	DELIVERY MODE
09/07/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/584,073	UTAS ET AL.	
	Examiner	Art Unit	
	MELANIE HAND	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 June 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1,4-16,23-28 and 36-42* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1,4-16,23-28 and 36-42* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The objection to claim 35 is moot in view of the cancellation of the claim.

2. The rejection of claims 18, 19, 30, 31, 34 and 35 under 35 U.S.C. 112 is moot in view of the cancellation of those claims. The rejection of claims 4, 5, 11, 24 and 25 under 35 U.S.C. 112 is moot in view of the amendment to the claims.

3. The rejection of claims 17 and 33 under 35 U.S.C. 102 is moot in view of the cancellation of those claims.

4. Applicant's arguments filed June 14, 2011 regarding the rejection of claims 1, 4-16, 23-28 under 35 U.S.C. 103 have been fully considered but they are not persuasive. Pages 10-15 appear to cite case law and any substantive arguments appear to be drawn to unexpected benefits which would need to be illustrated in an affidavit or declaration under 37 CFR 132 traversing the rejection of claim 1 over Israelsson I and Bongard since the combination meets all of the claim limitations. As to the argument on page 26 that the reference to saline in Israelsson I ('937) is clearly to normal saline and not hypertonic saline, and that Israelsson I does not disclose the recited concentration of osmolality increasing compound, the examiner disagrees that this is clear from Israelsson. While it may be clear to the applicant, Israelsson only mentions saline and the applicant is requested to cite the portions of Israelsson that the applicant believes excludes hypertonic saline as a wetting fluid option. The examiner believes that the saline disclosed by Israelsson is inclusive of normal and hypertonic saline, the two most likely types of saline one of ordinary skill in the art would employ as an osmolality increasing compound to the surface of the catheter. Bongard was then introduced to remedy the deficiency of Israelsson with regard to a particular concentration of osmolality-increasing compound. Applicant's

arguments regarding the rejection of claim 1 under Isralesson II ('494) appear to be the same as arguments presented with respect to the rejection of claim 1 over Israelsson I. As to arguments that one of ordinary skill in the art would not be motivated to use the hypertonic saline solution of Bongard as the wetting fluid because hypertonic saline is used only in select instances to rapidly treat hyponatremia in patients and it requires strong supervision, it is the examiner's position that it is entirely possible, because, again Israelsson only discloses saline, that one of ordinary skill in the art would use isotonic (normal) saline as the wetting fluid for a patient that does not suffer from hyponatremia and hypertonic saline for one that does. Further, it would readily be understood by one of ordinary skill in the art that an individual using this catheter is not inserting it him-or herself in the complete absence of trained health care personnel and is thus already under "strong supervision", wherein any complications from the use of hypertonic saline can readily be reversed. The balance of the applicant's arguments appear to again rely on unexpected results that would not be obtained or seen by the assembly of Israelsson I or II when using the hypertonic saline solution disclosed by Bongard as the disclosed saline wetting fluid.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 4-16 and 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Israelsson (WO 97/26937 A1) in view of Bongard (see attached PTO-892 form for full citation).

With respect to **claim 1:** Israelsson discloses a catheter assembly comprising a wetting fluid in sachet 6 (Page 10, lines 15-19); a catheter 3 having on its surface, on at least an insertable part thereof, a hydrophilic surface layer ('937, Page 6, lines 28-31, Page 10, lines 1-20); and a receptacle in the form of a receptacle 1 enclosing at least the insertable part of the catheter (Abstract). With regard to the limitation "providing low-friction surface character of the catheter by treatment with said wetting fluid", such a limitation constitutes functional language that is given little patentable weight herein. As Israelsson discloses a catheter with a hydrophilic surface layer and a wetting fluid that contacts said layer, a low-friction surface character of the catheter by treatment with said wetting fluid is necessarily provided. The wetting fluid comprises saline, which by its nature contains a dissolved osmolality-increasing compound such as sodium or potassium chloride. The assembly disclosed by Israelsson presents a storage state in which the wetting fluid is kept separated in sachet 6 from the hydrophilic surface layer of the catheter, and an activation state in which the wetting fluid is released form the sachet and brought into contact with said hydrophilic surface layer before an intended use of the catheter. ('937, Abstract)

Israelsson does not explicitly disclose that the total concentration of the dissolved osmolality-increasing compound(s) exceeds 600 mOsm/dm^3. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/dm^3).It is the examiner's position that since the solution is intended for contact with urine (as the wetting fluid layer on the outside of the catheter of Israelsson is) and is a saline solution (also disclosed by Israelsson as a solution for the wetting fluid), the hypertonic saline solution disclosed by Bongard is fully functional as a wetting fluid in the device of Israelsson. Bongard teaches that this solution is also effective to treat hyponatremia in a patient, which can be both detected and treated in a patient's urine. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Israelsson such that the wetting fluid saline solution is a hypertonic saline as disclosed by Bongard to lubricate as well as treat any sodium deficiency in the urine that could cause adverse health effects. The device of Israelsson as modified by Bongard thus discloses a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration exceeding 600 mOsm/dm^3 when the fluid is separate from at least the insertable part of the catheter.

With respect to **claims 4,18,24,36,38:** Israelsson does not explicitly disclose that the total concentration of the dissolved osmolality-increasing compound(s) exceeds 600 mOsm/dm^3. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/dm^3), which meets the narrower limitation of claims 4, 18, 24, 30 and 34, i.e. “exceeds 800 mOsm/dm^3. The motivation to modify the Israelsson assembly such that the saline wetting fluid is the hypertonic saline solution disclosed by Bongard is stated *supra*

with respect to claim 1.

With respect to **claims 5,19,25:** The device of Israelsson as modified by Bongard has a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration of 1,026 mOsm/dm^3 when the fluid is separate from at least the insertable part of the catheter, which is not in the range of 850-950 mOsm/dm^3. However applicant has not established any criticality for this particular range. The osmolality increasing compound concentration is a result-effective variable in that it dictates the rate and direction of diffusion of the compound. Thus this range is considered herein to be an optimization of a result-effective variable. Since hypertonic saline is any saline solution with NaCl concentration greater than 0.9%, and a 0.9% NaCl concentration corresponds to an osmolality substantially equal to urine, any hypertonic saline solution having an NaCl concentration lower than the 3% disclosed by Bongard but greater than 0.9% would still be hypertonic and thus effective to treat hyponatremia and lubricate the catheter. One of ordinary skill in the art could reasonably expect that there are hypertonic saline solutions with an NaCl concentration in this range of greater than 0.9% - 3% that also have a total concentration of osmolality-increasing compound within the claimed range, rendering claims 5, 19, 25, 31 and 35 unpatentable.

With respect to **claims 6 and 26:** Israelsson does not explicitly disclose that the total concentration of the dissolved osmolality-increasing compound(s) exceeds 600 mOsm/dm^3. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/dm^3), which meets the limitation of claims 4, 18, 24, 30 and 34, i.e. “greater than 600 mOsm/dm^3 and less than 1,500 mOsm/dm^3), . The motivation to modify the

Israelsson assembly such that the saline wetting fluid is the hypertonic saline solution disclosed by Bongard is stated *supra* with respect to claim 1.

With respect to **claim 7:** Israelsson discloses by reference to Johansson that said osmolality-increasing compounds is/are selected from the group consisting of urea, amino acids, mono and disaccharides, sugar alcohols, and non-toxic organic and inorganic salts or acids, polypeptides and mixtures thereof. ('771, Abstract)

With respect to **claim 8:** Israelsson discloses by reference to Johansson that said osmolality-increasing compound is sodium chloride. ('771, Abstract)

With respect to **claim 9:** Israelsson discloses by reference to Johansson that the osmolaltiy increasing compound, and thus the wetting fluid, when the compound comes in contact with the water in cavity 5, further comprises a polymer. ('771.Abstract)

With respect to **claim 10:** The polymer disclosed by Israelsson by reference to Johansson is a hydrophilic polymer. ('771, Page 2, lines 46, 47)

With respect to **claim 11:** The amount of polymer disclosed by Israelsson by reference to Johansson, PVP, is present in a wetting fluid in an amount of 5% w/v. Since the solvent is water (density=100 g/100 mL), the PVP is present in an amount of 5 g PVP/100 g water, which falls within the claimed range of 0-20% of weight and most preferably in the range 5-15%, and typically about 10%.

With respect to **claim 12:** The wetting fluid 9 disclosed by Israelsson by reference to Johansson having the osmolality-increasing compound therein is a sterile aqueous solution, i.e. it is a water-based liquid.

With respect to **claim 13:** The catheter 7 disclosed by Israelsson is a urinary catheter. With regard to the limitation "adapted for intermittent use", a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. Thus since Israelsson meets the limitation of a urinary catheter and no additional structure is claimed, the catheter of Israelsson is necessarily adapted for intermittent use as well.

With respect to **claim 14:** The wetting receptacle 5 disclosed by Israelsson encloses the entire catheter. (Fig. 1)

With respect to **claim 15:** The receptacle 5 is formed by sealing packaging material layers around the catheter, forming a cavity where the wetting fluid will later be housed, thus the receptacle necessarily entirely encloses said wetting fluid. (Page 9, line 34 – Page 10, line 7)

With respect to **claim 16:** The catheter assembly disclosed by Israelsson '937 meeting all of the structural limitations of claim 1 and further comprises a separate wetting fluid container, sachet 6, which encloses said wetting fluid and which forms part of said catheter assembly. (Fig. 1, Page 10, lines 15-20)

With respect to **claim 23:** Israelsson discloses a method for producing a catheter assembly, comprising: providing a receptacle, cavity 5 (Page 10, lines 2-7); providing a hydrophilic catheter 7 (Abstract); providing a fluid 9 that interacts with the catheter hydrophilic coating to comprise an osmolality-increasing compound meeting the limitation of a wetting fluid (taught by reference to Johansson '771); arranging at least an insertable part of the catheter in the receptacle 5 (Fig. 1) and arranging said wetting fluid by placing the fluid in receptacle 5 as a part of said catheter assembly; wherein the assembly disclosed by Israelsson presents a storage state in which the wetting fluid is kept separated in sachet 6 from the hydrophilic surface layer of the catheter, and an activation state in which the wetting fluid is released form the sachet and brought into contact with said hydrophilic surface layer before an intended use of the catheter. ('937, Abstract); said wetting fluid, upon contact with the hydrophilic coating of the catheter 7, comprising at least one dissolved osmolality-increasing compound, i.e. sodium chloride. The concentration of the osmolality-increasing compound in the Johansson solution is 0.680 mOsm/dm^3, which does not fall within the claimed range. Bongard discloses a hypertonic saline solution for replacing sodium lost from urine comprising a 3% NaCl solution with a total concentration of osmolality-increasing compound of 1,026 mOsm/L (=1,026 mOsm/dm^3).It is the examiner's position that since the solution is intended for contact with urine (as the wetting fluid layer on the outside of the catheter of Israelsson is) and is a saline solution (also disclosed by Israelsson as a solution for the wetting fluid), the hypertonic saline solution disclosed by Bongard is fully functional as a wetting fluid in the device of Israelsson. Bongard teaches that this solution is also effective to treat hyponatremia in a patient, which can be both detected and treated in a patient's urine. Therefore, it would be obvious to one of ordinary skill in the art to modify the device of Israelsson such that the wetting fluid saline solution is instead a hypertonic saline as disclosed by Bongard to lubricate as well as treat any sodium deficiency in the urine that could cause

adverse health effects. The device of Israelsson as modified by Bongard thus discloses a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration exceeding 600 mOsm/dm^3 when the fluid is separate from at least the insertable part of the catheter.

With respect to **claim 27:** Israelsson discloses by reference to Johansson that said osmolality-increasing compounds is/are selected from the group consisting of urea, amino acids, mono and disaccharides, sugar alcohols, and non-toxic organic and inorganic salts or acids, polypeptides and mixtures thereof. ('771, Abstract)

With respect to **claim 28:** The wetting fluid 9 disclosed by Israelsson by reference to Johansson having the osmolality-increasing compound therein is a sterile aqueous solution, i.e. it is a water-based liquid.

With respect to **claims 37,39:** The device of Israelsson as modified by Bongard has a wetting fluid having a dissolved osmolality-increasing compound (NaCl) at a total concentration of 1,026 mOsm/dm^3 when the fluid is separate from at least the insertable part of the catheter, which is not 900 mOsm/dm^3 or in the range of "about 900 mOsm/dm^3". However applicant has not established any criticality for this particular range. The osmolality increasing compound concentration is a result-effective variable in that it dictates the rate and direction of diffusion of the compound. Thus this range is considered herein to be an optimization of a result-effective variable. Since hypertonic saline is any saline solution with NaCl concentration greater than 0.9%, and a 0.9% NaCl concentration corresponds to an osmolality substantially equal to urine, any hypertonic saline solution having an NaCl concentration lower than the 3% disclosed by

Bongard but greater than 0.9% would still be hypertonic and thus effective to treat hyponatremia and lubricate the catheter. One of ordinary skill in the art could reasonably expect that there are hypertonic saline solutions with an NaCl concentration in this range of greater than 0.9% - 3% that also have a total concentration of osmolality-increasing compound within the claimed range, rendering claims 5, 19, 25, 31 and 35 unpatentable.

With respect to **claim 40:** The polymer disclosed by Israelsson by reference to Johansson is the same type of hydrophilic polymer as in the hydrophilic coating of the catheter. ('771, Page 2, lines 46, 47)

With respect to **claim 41:** The amount of polymer disclosed by Israelsson by reference to Johansson, PVP, is present in a wetting fluid in an amount of 5% w/v. Since the solvent is water (density=100 g/100 mL), the PVP is present in an amount of 5 g PVP/100 g water, which falls within the claimed range of 5-15%.

With respect to **claim 42:** The amount of polymer disclosed by Israelsson by reference to Johansson, PVP, is present in a wetting fluid in an amount of 5% w/v. Since the solvent is water (density=100 g/100 mL), the PVP is present in an amount of 5 g PVP/100 g water, which does not fall within the claimed range of about 10%. However the applicant has not established sufficient criticality for this range as opposed to all other disclosed and recited ranges of polymer content in the coating. As the polymer/solvent ratio alters the lubriciousness of the coating which in turn alters the smoothness and lack of irritation upon insertion of the catheter in the urethra of a patient, the polymer content is considered herein to be a result effective variable. One of ordinary skill in the art would be motivated to modify the polymer content to be higher to act as

an efficient carrier for the other components of the wetting fluid and to ensure the wetting fluid will remain on the surface of the catheter for a sufficient length of time to increase its lubriciousness. It has been held that the discovery of an optimum value of a result-effective variable in a known process is ordinarily within the skill of the art. See *In re Boesch and Slaney*, 205 USPQ 215 (C.C.P.A. 1980)

Conclusion

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELANIE HAND whose telephone number is (571)272-6464. The examiner can normally be reached on Mon-Thurs 8:00-5:30, alternate Fridays 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Melanie J Hand/
Primary Examiner, Art Unit 3761